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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,885	10/19/2004	Martin Purpura	5942-83616	4212

22242 7590 03/17/2009

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LASALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,885	PURPURA ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-21 and 23-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-21 and 23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/Remarks, amended claims and RCE filed on 10/28/08 is acknowledged.

Claims 12 and 22 have been cancelled.

Claims **1-11, 13-21 and 23-37** are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims **1-11, 13-21 and 23-37** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 6, 34 and 36 recite the various components that provide stable matrix, however no specific recitation of carbohydrate, polymner mineral etc. has been cited in the claims. The claims recite various components as supporting material, however no specific components are disclosed. Due to the lack of specific ingredients the structural and functional relation cannot be deduced. In order to provide meaningful search, the

examiner suggests specifying individual components which are response for specific function claimed. The claims1 34 and 36 recites the limitation as >= 5% by weight acetone insoluble phospholipid components based on a starting material of the acetone insoluble phospholipid components as a bioactive agent.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11, 13-21 and 23-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims1, 6, 34 and 36 recites the limitation as >= 5% by weight acetone insoluble phospholipid components based on a starting material of the acetone insoluble phospholipid components as a bioactive agent which make the claim indefinite. It is not clear what ingredients are claimed in starting material and in what amount. There are various phospholipids which are acetone insoluble, therefore it is not clear which phospholipid is the applicant claiming. The metes and bounds of claim are not defined. For meaningful search, the examiner suggests reciting specific ingredients with specific amounts. The word stable is not clear, stable in what sense? Claim 15 recites sup[porting material, there is no antecedent basis for this claim, as such the claim is indefinite.

Claims recite polyphenols, trace elements and mineral substances which make the claim indefinite metes and bounds of claims are not defined. Appropriate correction is required.

DOUBLE PATENTING

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13-21 and 23-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-33 of copending Application No. 10/511884 Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending application and instant application have overlapping subject matter. The

copending application varies in terms of diameter of matrix. Optimization of matrix would have been within the purview of skilled artisan at the time of instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-11, 13-21 and 23-37 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Geiss et al. (US PG pub.2004/0120985 A1) in view of Kiliaan et al. (WO 01/84961 A2).

Geiss et al. discloses functional food for the cognitive functional capacity comprising carbohydrate, proteins, phosphatidylserine, vitamins and fat. The functional food products disclosed are in the form of milk; diet foods, dairy products etc. (see claims). The protein content in food bar is disclosed to be of at least 10 wt% and fat of minimum 15 wt%, preferably 27 wt % and bar can be enriched with vitamins (see page 2 , paragraph [0023] and claims. The water content of less than 3% increases the **stability of phosphatidyl serine** and the shelf life can be more than one year (see

page 2, paragraph [0026]. The reference discloses the following ingredients and amounts.

The ingredients per 100 g of the chocolate bar are: fructose syrup, sugar, powdered skim milk, cocoa butter, powdered milk, milk protein, sweet whey powder, dextrose, hydrogenated vegetable oil, cocoa mass, maltodextrin, modified starch, rice extrudate, 1.4 g of lecithin extract, coffee extract, flavor compound, emulsifier lecithins, 120 mg of vitamin C, dried egg albumin, 13.2 [mg] of pantothenate, 13 mg of vitamin E, 8 mg of niacin, 4 mg of vitamin B1, 4 mg of vitamin B6 and 200 mg of phosphatidyl serine from lecithin extract. The product size of the bar is preferably 35 g, see paragraph [0052].

The reference teaches the following on paragraph [0039] Based on animal experimental studies, the following statements can be considered confirmed facts. The administration of phosphatidyl serine protects against neuron atrophy, partially prevents the age-related breakdown of the receptors for the nerve growth factor, promotes the formation of nerve growth factors (an effect specific to phosphatidyl serine which was not identified for other phospholipids), normalizes the cholesterol/phospholipid ratio in the aging brain, improves the ATPase-dependent ion transport via the cell membrane, and normalizes the protein kinase C balance.

The reference does not teach mineral components, hydrophobic material such as triglyceride.

Kiliaan et al. discloses a preparation suitable for the prevention and/or treatment of vascular disorders, comprising the following fractions: fraction a) long chain

polyunsaturated fatty acids; fraction b) phospholipids, the fraction contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, fraction c) compounds which are a factor in methionine metabolism, which fraction contains at least one member selected from the group consisting of folic acid, vitamin B 12, vitamin B6, magnesium and zinc (abstract). The preparation of the invention can be a pharmaceutical, dietetic as well as a nutritional preparation. The products can have the form of a liquid, powder, bar, cookie, sweetie, concentrate, paste, sauce, gel, emulsion, tablet, capsule, etc. to provide the daily dose of the bioactive components either as a single or in multiple doses (page 6, lines 1-5). Triglyceride is listed on page 6, line 14. The composition contains zinc and copper (see page 9, lines 1-5). Kiliaan et al. discloses on page 12, various diseases and symptoms that can be treated are cognitive degeneration and improper functioning associated with kidneys, liver, stomach etc. Another advantage of the composition disclosed is in normalizing plasma cholesterol levels (see page 6, lines 17-18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate mineral components, hydrophobic material such as triglyceride as taught by Kiliaan et al. to the composition of Geiss et al. One would have been motivated to do so because the prior art teaches that such composition is suitable for treating cognitive degeneration.

Based on the teachings of Kiliaan et al., it would have been obvious to one of ordinary skill in the art to prepare a functional food in any form such as liquid, bar or

cookie etc. as claimed comprising mineral components. One skilled in the art would have optimized the various amounts of the components by doing experimental manipulations in order to arrive at the effective amount of the functional food. Regarding the specific phospholipids claimed in claim 11, it is the position of the examiner that since the prior art teaches inclusion of various phospholipids, inclusion of the specific phospholipids would have been obvious to the formulation taught by the combination of references in the absence of unexpected results.

Response to Arguments

9. Applicant's arguments filed 10/28/08 have been fully considered but they are not persuasive.

Applicants argue that Geiss et al. do not teach any matrix which is suitable for stabilizing the phospholipids.

Applicants arguments are not persuasive because Geiss et al. specifically teach functional food for the cognitive functional capacity comprising carbohydrate, proteins, phosphatidylserine, vitamins and fat and disclose that the water content of less than 3% increases the **stability of phosphatidyl serine** and the shelf life can be more than one year (see page 2, paragraph [0026]. The reference also discloses several ingredients added to phosphatidyl serine. Applicant is looking for specific recitation of matrix, however the teachings of prior art do not exclude the same by not teaching coated or layered product. Besides, claims 1, 34 and 36 as recited does not specify any particle

size of matrix or any specific ingredients in specific amounts to account for stable matrix or supporting material.

With respect to Kiliaan et al. applicants argue that Killiaan never describes stabilizing the phospholipid as a part of a matrix (the phopsholipid on a support) as opposed to just mixing the ingredients. This argument is not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., stabilizing the phospholipid as a part of a matrix (the phopsholipid on a support) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims 1 and 34 only recite a food product comprising a phospholipid –containing stable matrix comprising unmodified carbohydrates etc. and acetone insoluble phospholipid components.

JP 61078351 has been excluded from the rejection; as such the arguments regarding the same are moot.

10. Claims 32 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Geiss et al. (US PG pub.2004/0120985 A1) in view of Kiliaan et al. (WO 01/84961 A2) and further in view of De Simon et al. (US 20020031507 A1).

The references taught above do not disclose Sphingomyelin.

De Simon et al. teaches composition for food preparation and teaches that the invention can also contain bile acids, in particular ursodeoxycholic acid, pectin,

sphingomyelin or its compounds, drugs or foods containing sphingomyelin, arginine deiminase, fatty acids, polyunsaturated fatty acids, non fermented sugars, in particular lactulose, cholesterol inhibitors, ceramidase inhibitors, protease inhibitors, immunomodulators, anti-carcinogenic agents, vitamins, growth factors, surfactants, cereals, fibre, emulsifiers, stabilizers, lipids, antioxidants, preservatives, free-radical neutralizers and/or vaso-protectors ([0020]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate Sphingomyelin in the teachings of primary references because Sphingomyelin the secondary reference is also directed to food preparation.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612